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**Patent and Trademark Office**

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/153,133	09/15/98	LEE	D 04712/018002

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HM12/0912

EXAMINER

SHARAREH, S

ART UNIT	PAPER NUMBER
1619	10

DATE MAILED: 09/12/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.  
**09/153,133**

Applicant(s)  
**L et al**

Examiner  
**Shahnam Sharar h**

Group Art Unit  
**1619**



☒ Responsive to communication(s) filed on 19 Jun 2000

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claim

☒ Claim(s) 1-3, 5, 6, 8-31, and 33-44 is/are pending in the applicat

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 1-3, 5, 6, 8-31, and 33-44 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 7

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

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### **DETAILED ACTION**

Amendment filed on June 23, 2000 has been entered. Accordingly, claims 1, 13-15, 26-28, 33, and 37 are amended, claims 38-44 are added. Claims 4, 7, 32 are canceled. claims 1-3, 5-6, 7-31, and 33-44 are now pending.

1. Claims 1, 13-15, 38-44 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The recitation of "An injectable paste having a solids content of greater than 40 wt%" and "self-setting" is not supported in the original specification. Applicant's reference to the related parts of the specification does not teach the recited elements.
2. Applicant's arguments in respect to the rejection made under 35 U.S.C. 102(b) as being anticipated by Towey et al US Patent 2,967,802 has been considered and were found persuasive in view of the new matter added, because Towey et al do not disclose an injectable past having a solid content of greater than 40 wt%. Accordingly, said rejection is withdrawn, however, the instant rejection is restated below in the form of 35 U.S.C. 103(a) obviousness rejection.

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3. Applicant's arguments in respect to the rejection made under 35 U.S.C. 102(b) as being anticipated by Wilkinson et al US Patent 4,110,432 has been considered and were found persuasive in view of the amendments. Said rejection is withdrawn.

6. Applicant's arguments in respect to the rejection made under Applicant's arguments in respect to the rejection made under 35 U.S.C. 102(b) as being anticipated by Gupta et al (Vaccine Design Chapter 8 pp 229-248 1995.) has been considered and were found persuasive in view of the new matter added, because Gupta et al do not disclose an injectable paste having a solid content of greater than 40 wt% that is self-setting. Accordingly, said rejection is withdrawn, however, the instant rejection is restated below in the form of 35 U.S.C. 103(a) obviousness rejection has been considered and were found persuasive in view of the new matter added, because Gupta et al do not disclose an injectable paste having a solid content of greater than 40 wt% that is self-setting. Accordingly, said rejection is withdrawn, however, the instant rejection is restated below in the form of 35 U.S.C. 103(a) obviousness rejection.

7. Applicant's arguments in respect to the rejection made under U.S.C. 103(a) as being unpatentable over Reyveld US Patent 4,016,252, Gupta et al (Vaccine Design Chapter 8 pp 229-248 1995.), Wilkinson et al US Patent 4,110,432 and Kossovsky et al US Patent 5,462,751 has been considered and were found persuasive in view of the new matter added, because none of the references teach an injectable paste having a solid content of greater than 40 wt% that is self-setting. Accordingly, said rejection is withdrawn, however, the instant rejection is restated below in the form of 35 U.S.C. 103(a) obviousness rejection. §§

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***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-2, 6-7, 10, 13-14, 26-27, 34, 37 rejected under 35 U.S.C. 103(a) as being unpatentable over Towey et al US Patent 2,967,802.

6. Claims 1-2, 6, 10-11, 13-15, 19, 23-24, 26-30, 34-35, 37 rejected under 35 U.S.C. 103(a) as being unpatentable over Gupta et al (Vaccine Design Chapter 8 pp 229-248. 1995.)

The teachings of Towey et al and Gupta were discussed previously. Towey et al and Gupta teach solid concentrations of up to 15% in their adjuvant composition. Although Neither Gupta nor Towey et al teach solid concentrations of 40% and above, it would have been obvious to one of ordinary skill in the art to optimize the workable range of the solid content in their adjuvant composition by routine experimentation. ~~It~~ is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA1955) In this case, both Towey et al and Gupta teach suitable amorphous calcium phosphate as an adjuvant to induce an immune response, accordingly, it would have been obvious to optimize the immunogenicity of the adjuvant by optimizing the concentration of its solid content.

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~~7. Claims 1-2, 6, 10-11, 13-15, 19, 23-24, 26-30, 34-35, 37 rejected under 35 U.S.C. 103(a) as being unpatentable over Gupta et al (Vaccine Design Chapter 8 pp 229-248, 1995.)~~

8. Claims 1-3; 5-6, 7-31, and 33-44 rejected under 35 U.S.C. 103(a) as being unpatentable over Towey et al US Patent 2,957,802 and Gupta et al (Vaccine Design Chapter 8 pp 229-248, 1995.) in view of Lee et al US Patent 5,676,976.

The teachings of Gupta et al and Towey et al were discussed previously. The teachings of Lee et al are relied upon to indicate the suitability of amorphous calcium phosphate with high content of solid particles as an adjuvant in vaccine formulations. More specifically, Lee et al teach the use of injectable paste form of amorphous calcium phosphate solid with protein or polypeptide components (see example 8>).

Examiner takes the position that peptides encompassing those that can cause a biological activity (including various cytokines eg. IL-1, IL-2, IL-3, etc.) can be employed in a manner known in the art to stimulate an immune response of a host subject by acting as a vaccine in combination with an adjuvant.

Gupta, Towey and Lee all teach various methods of utilizing calcium phosphate in pharmaceutical formulation, therefore, they are viewed as being in the same field of endeavor.

It has been established that the prior art can be modified or combined to reject claims as prima facie obvious as long as there is a reasonable expectation of success, therefore, although Gupta or Towey do not disclose methods of preparing a vaccine comprising at a first adjuvant with high concentrations of solid or a composition with least two adjuvant, one skilled in the art

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would have been motivated to combine various known components taught by Gupta, Towey, and Lee and formulate compositions for stimulating an immune in a mammal that comprise calcium phosphate adjuvants. As taught by Towey and further Gupta, calcium phosphate is a suitable adjuvant and can be used in combination with a second adjuvant. Lee teaches the use of amorphous calcium phosphate in combination with peptides. Therefore, it would have been obvious to one skilled artisan to create immune response inducing adjuvant compositions having high concentration of solid particles and comprise a combination of adjuvant moieties, because prior art teachings indicate an enhanced potency in prophylactic medicine when such combinations have been used.

### *Conclusion*

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action, because it modified the scope of independent claims. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

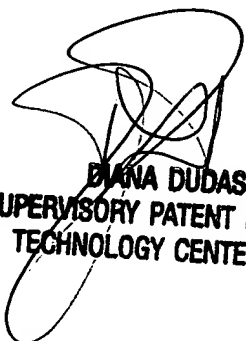
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh, PharmD whose telephone number is (703) 306-5400. The examiner can normally be reached on Monday to Friday from 8:30 a.m. to 5:00 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Diana Dudash can be reached on 703-308-2328. The fax phone number for this Group is 703-308-2328. Any inquiry of a general nature of relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is 703-308-1235.

*sjs 9/11/2000*



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